

AUG - 8 2006

510(k) Summary

Introduction According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7688

Contact Person: Dimitris Demirtzoglou

Date Prepared: March 10, 2006

2) Device name Proprietary name: ONLINE TDM Valproic Acid

Common name: Enzyme Immunoassay, Valproic acid

Classification name: Enzyme Immunoassay, Valproic acid

3) Predicate device We claim substantial equivalence to the currently marketed COBAS INTEGRA Valproic Acid (K951595).

Continued on next page

510(k) Summary, Continued

4) Device Description

The ONLINE TDM Valproic Acid assay is for the quantitative determination of valproic acid in human serum or plasma on Roche automated clinical chemistry analyzers. The proposed labeling indicates the Roche Hitachi 911, 912, 917 and Modular P analyzers can be used with the Roche ONLINE TDM Valproic Acid reagent kits.

The assay is based on a homogeneous enzyme immunoassay technique used for the quantitative analysis of valproic acid (free and protein-bound) in human serum or plasma. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the sample can be measured in terms of enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the coenzyme functions only with the bacterial (*Leuconostoc mesenteroids*) enzyme employed in the assay.

5.) Intended Use

The ONLINE TDM Valproic Acid assay is for the quantitative determination of valproic acid in human serum or plasma on Roche automated clinical chemistry analyzers.

Continued on next page

510(k) Summary, Continued

6.) Comparison to the Predicate Device The Roche ONLINE TDM Valproic Acid assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Roche COBAS INTEGRA Valproic Acid (K951595).

The Roche ONLINE TDM Valproic Acid assay was evaluated for several performance characteristics including precision, lower detection limit, method comparison, specificity, and interfering substances. All of the evaluation studies gave acceptable results compared to the predicate device. These experiments provide evidence that the Roche ONLINE TDM Valproic Acid assay is substantially equivalent to the currently marketed Roche COBAS INTEGRA Valproic Acid assay. The following table summarizes the precision and method comparison results.

	Roche ONLINE TDM Valproic Acid			Roche COBAS FP Valproic Acid (Predicate)		
NCCLS Precision, Within run	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	33.3	74.9	107.8	26.2	60.1	102.0
SD (µg/ml)	0.69	1.42	2.11	0.46	1.05	2.46
CV%	2.1	1.9	2.0	1.7	1.7	2.4
NCCLS Precision, Total	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	33.3	74.9	107.8	26.2	60.1	102.0
SD (µg/ml)	2.07	3.75	5.02	0.61	1.26	2.46
CV%	6.2	5.0	4.7	2.3	2.1	2.4
Method Comparison	<u>Linear Regression: ONLINE TDM Valproic acid Vs. COBAS FP Valproic acid</u> N=54, Range = 15.0 -132.1 µg/ml $y = 1.017x - 0.053$ $r = 0.995$ SD (md 95) = 4.801			<u>Linear Regression: COBAS FP Valproic acid Vs. COBAS FARA II</u> N=207, Range = 3.2 - =150 µg/ml $y = 1.041x - 1.365$ $r = 0.998$		



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Dimitris Demirtzoglou
Regulatory Affairs Consultant
Roche Diagnostics, Inc.
9115 Hague Road
Indianapolis, IN 46250-0457

AUG - 8 2006

Re: k060690
Trade/Device Name: ONLINE TDM Valproic Acid
Regulation Number: 21 CFR§ 862.3645
Regulation Name: Neuroleptic drugs radioreceptor assay test system
Regulatory Class: Class II
Product Code: LEG
Dated: July 19, 2006
Received: July 20, 2006

Dear Mr. Demirtzoglou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

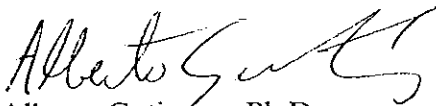
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alberto Gutierrez", with a stylized flourish at the end.

Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060690

Device Name: ONLINE TDM Valproic Acid

Indications For Use:

The ONLINE TDM Valproic Acid assay is for the quantitative determination of valproic acid in human serum or plasma on Roche automated clinical chemistry analyzers. Measurements obtained from this device are used in the diagnosis and treatment of valproic acid overdose and in monitoring the levels of valproic acid to help ensure appropriate therapy.

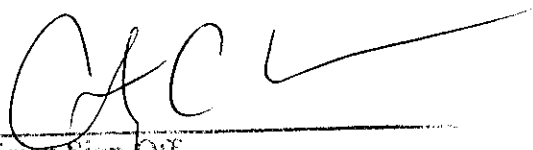
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060690

Page 1 of 1